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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HILL, KEVIN KAI

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
07/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/535,395	SEVE ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7, drawn to a method of using an isolated polynucleotide or its corresponding isolated polypeptide as a specific marker for the beta cells of pancreatic islets of Langerhans.

Group II, claims 8-9, 11-12, 30-32 and 50, drawn to an isolated polynucleotide, an expression vector comprising an insert consisting of said isolated polynucleotide, a cell modified with said polynucleotide, and a transgenic non-human organism.

Group III, Claim 10, drawn to a pair of primers for amplifying nucleic acids corresponding to the polynucleotides of claim 1.

Group IV, Claims 13-18, drawn to a method for determining the transcription profile of a gene in a biological sample, said method comprising bringing nucleic acids obtained from said sample into contact with a labeled nucleic acid probe.

Group V, Claim 19, drawn to a kit of reagents, said kit comprising at least one nucleic acid probe.

Group VI, Claim 20, drawn to a DNA chip comprising at least one polynucleotide.

Group VII, Claim 21, drawn to a method of using a polynucleotide for preparing a DNA chip.

Group VIII, Claim 22, drawn to a method of using a polynucleotide as a means for studying a biological process.

Group IX, Claims 23-25 and 50, drawn to an isolated protein having the sequence of SEQ ID NO:2, or a variant or fragment thereof.

Group X, Claim 26, drawn to a protein chip comprising a protein of SEQ ID NO:2, 7, 8, 9 or 10.

Group XI, Claim 27, drawn to a method of using a protein or protein fragment for preparing a protein chip.

Group XII, Claims 28-29, drawn to a method of using a protein or protein fragment or protein chip for detecting the presence of antibodies in the serum of an individual.

Group XIII, Claims 33-34, drawn to a method of making a protein from a cell or non-human transgenic organism.

Group XIV, Claims 35, 40 and 50, a monoclonal or polyclonal antibody, and a kit comprising said monoclonal or polyclonal antibody.

Group XV, Claim 36, drawn to a protein chip comprising at least one monoclonal or polyclonal antibody.

Group XVI, Claim 37, drawn to a method of using an antibody for preparing a protein chip.

Group XVII, Claim 38, drawn to a method of using a polypeptide or antibody for detecting and/or purifying a protein.

Group XVIII, Claim 39, drawn to a method for detecting any protein or protein fragment in a biological sample.

Group XIX, Claims 41 and 43-45, drawn to a method of using an antibody for detecting and/or sorting islets of Langerhans or beta cells.

Group XX, Claim 42, drawn to a method of using an antibody for analyzing the differentiation of stem cells into pancreatic islet cells.

Group XXI, Claims 46-47, drawn to a method of screening for a chemical or biochemical compound that interacts with a polynucleotide.

Group XXII, Claims 48-49, drawn to a method of screening for a chemical or biochemical compound that interacts with a protein.

Group XXIII, Claim 51, drawn to a method of making a medicinal composition for the treatment of disease.

Group XXIV, Claim 52, drawn to a method of using a composition for determining an anomaly of a gene encoding a protein.

2. The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:
"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

The claims are drawn to a genus of structurally distinct compositions including a genus of structurally and functionally distinct polynucleotides that encode polypeptide, do not encode polypeptides or encode antisense RNA molecules, a genus of structurally distinct polypeptides,

antibody molecules, DNA chips and protein chips. Furthermore, the methods are designed to solve distinctly different problems, e.g. identifying beta cells of pancreatic islets of Langerhans, transcription profiling, making transgenic non-human organisms, or screening chemical compounds. As such, the special technical features are non-identical because one of ordinary skill in the art would not expect a protein-encoding polynucleotide to have the same biological effect as a polynucleotide encoding an antisense RNA, for example.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. **Claim 30 is generic to the following disclosed patentably distinct species:** cloning and/or expression vector species comprising the polynucleotide of Claim 8, wherein Applicant contemplates a genus of vectors (pg 20, lines 39-pg 21, line 15), with specific molecules

disclosed on pages 19-23. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed cloning and/or expression vector species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 31-32 are generic to the following disclosed patentably distinct species: host cells and transgenic organisms comprising the polynucleotide of Claim 8, wherein Applicant contemplates a multitude of cells and organisms (pg 21, lines 29-pg 22, line 10). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed host cell and transgenic organism species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species:

i) polynucleotide and polypeptide species to be used in the method of Claim 1, as recited in Claims 1-7,

ii) polynucleotide species, as recited in Claim 8, that is encoded by the vector of Claim 30, used in the method of Claims 13, 16, 21-22 and 46-47, and/or encodes a polypeptide of Claims 23, 26-29, 33-35, 39, 48-49,

iii) primer pairs, as recited in Claim 3, as applied to Claims 10, 13 and 16,

iv) alternative reagent species present in the kit of Claim 19,

v) polypeptide species, as recited in Claims 24-25 or encoded by a polynucleotide of Claim 8, as applied to the inventions of Claims 23, 26-29, and 33-35, 39, 48-49,
vi) direct or indirect interactions, as recited in Claims 46-49,
vii) *in vitro* or *in vivo* interactions, as recited in Claims 46-49,
viii) alternative test reagent species, specifically a polynucleotide, a cell, a transgenic organism or a DNA chip, as recited in Claims 46-47,
ix) alternative test reagent species, specifically a polypeptide, a cell, a transgenic organism or a protein chip, as recited in claims 48-49, and
x) alternative product species for use in the methods, specifically a polynucleotide, a polypeptide, an antibody or a cell, as recited in Claims 51-52.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed species **from each of (i)-(x) according to the elected invention** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Q. JANICE LI, M.D.
PRIMARY EXAMINER